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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,205	04/24/2008	Ulrich Schwaneberg	Q96421	6752

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
11/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/588,205	SCHWANEBERG ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/2/06; 8/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: In re Alonso 88 USPQ2d 1849-1854 (Fed Cir 2008).

DETAILED ACTION

Applicant's response to restriction requirement and amendment of 9/20/10 is entered.

Claims 1-10 are amended and presently pending.

Election/Restriction

The Examiner has reviewed Applicant's response and the amendment, and has decided that the Art to make the rejection is one of obviousness and it would be easier to rejoin the inventions rather than argue the base restriction requirement. Therefore, all claims are rejoined.

IDS

Several references in the IDS of 8/17/07 have not been considered because the document cited is not provided with a proper author, assignee, or inventor as is required by the MPEP. Those references have been crossed off.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 recites "an pore diameter", while proper English is "a pore diameter". Appropriate correction is required.

Specification

The specification is objected to for not containing a sufficiently detailed description of the claimed invention. To wit, the abstract is so broad as to read on activated carbon filters, and has no indication of the claimed invention's particulars.

Drawings

The drawings are objected to.

Figure 1 is too detailed at its size to be reduced to 1/3rd its original size and still elucidate the details.

Figures 2-6 contain characters which are below 1/8th an inch in height and will not be compressible to 1/3rd their original size. In fact, many characters are not legible at their current size.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application for the reasons above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a generic enantioselective pore. The specification provides one example, Maltoporin (e.g., paragraph 44 of the publication), and states that by incorporating suitable amino acids, other transmembrane proteins or structures which were not previously enantioselective, can be made so, and that in the future, more enantioselective proteins may be found (e.g., Id.).

However, no example of a transmembrane protein or other trnasmembrane structure which can be modified by amino acids to become enantioselective is provided, and it is axiomatic that future-found enantioselective pores cannot be possessed.

Still further, the Examiner has found no more evidence of enantioselective pores in the literature, and still further, *In re Alonso*, 88 USPQ.2d 1849 (Fed. Cir. 2008), makes clear that a single species does not provide sufficient written description for a genera, much less an absence of species.

Hence, given the only description of maltoporin, the Artisan would not have understood Applicant to have been in possession of the genera of enantioselective pores presently claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4 and 6-11 specifically encompass, or specifically require a pore which allows nucleic acids to traverse membrane. To wit, e.g., Claim 6 requires a positively charged oligomer for binding the substance, which may be polylysine (Claim 7), and the substance to be bound is a nucleic acid (Claim 9), and the substance released is a nucleic acid (Claim 11).

The specification only provides FhuA as a channel for such nucleic acids to traverse. Moreover, the Art provides no more channels which fit into liposomes. It is clear that these channels are not well known in the Art.

Finally, *In re Alonso*, 88 USPQ.2d 1849 (Fed. Cir. 2008), makes clear that a single species does not provide sufficient written description for a genera, much less an absence of species.

Therefore, the Artisan would not have understood Applicant to have been in possession of a generic nucleic acid pore, which is required to be present, or specifically encompassed, by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al.

Anderson teaches nanopourous particles with a retained target (e.g., TITLE). Such particles may be utilized in chemical isolation or cleanup (p. 9, paragraph 2). The chemical is taught to diffuse within the pourous nanostructured liquid or liquid crystalline particle or material and is bound by the target (p. 9, paragraph 2). The target is substantially retained within the nanoporous particle (e.g., ABSTRACT). Hence, the chemical can bind to the target and be held within the nanoparticle and isolated from the bulk media (e.g., p. 11, last paragraph).

What Anderson does not teach is to utilize a vesicle containing a target molecule bound to the interior of the vesicle, in order to allow the medium inside the particle to be the same as the bulk medium. What Anderson teaches is liquid crystalline mediums, which are naturally segregated from the bulk medium (e.g., pp. 12-13).

Meier teaches vesicles made of amphiphilic tri-block copolymers (e.g., ABSTRACT). Molecules, such as membrane proteins may be incorporated into the walls of the nanocapsules made (e.g., ABSTRACT). The nanocapsules may also contain a gating function protein, e.g., porins (e.g., p. 16, paragraph 4). Meier teaches at least one use for these vesicles includes removal of contaminants (e.g., p. 16, paragraph 7).

With the combination of teachings, the Artisan would be aware that a vesicle could be made similar to Meier, and containing an internally-linked ligand which binds to a target moleucle, and containing pores large enough to diffuse a target molecule. The Artisan would be

motivated to do so to product isolation or chromatography. Moreover, the Artisan would have a reasonable expectation of success, as the various components are utilized for art-recognized purposes.

With regard to Claim 2, it is noted that all substances bind reversibly through at least one of these interactions, and therefore, it is inherent that the target will bind the ligand through these interaction(s).

With regard to Claim 3, porins are transmembrane proteins.

With regard to Claim 4, ompF porins have pore diameters of 1.1nm at their narrowest constriction, but also contain areas of much larger diameters.

With regard to Claim 8, it is inherent in the methods of chromatography and removal of contaminants, that the substance to be isolated must come in contact with the vesicle.

Maltporin

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., as applied to claims 1-4 and 8 above, and further in view of Danelon, et al. (2003) Journal of Biological Chemistry, 278(37): 35542-51.

As shown above, the base claims are obviated, but the use of an enantioselective channel is not.

However, Danelon teaches one such enantioselective channel, maltoporin, and its orientation in the membrane (e.g., ABSTRACT).

Hence, it would have been obvious to further modify the invention to utilize maltoporin as the pore. The Artisan would do so to isolate maltodextrins from bulk media in separations or chromatography. Moreover, the Artisan would have a reasonable expectation of success, as the various components are utilized for Art-recognized purposes.

Nucleic Acid Isolation with polylysine

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., as applied to claims 1-4 and 8, above, and further in view of Locher, et al. (1998) Cell, 95: 771-78 and Cotton, et al. (2001) Current Protocols in Human Genetics, Chapter 12, Unit 12.3, Supplement 11, Wiley Online Library, 12.3.1-12.3.33, John Wiley & Sons, Inc.

As shown above, the base references are obviated, however, the use of a nucleic acid pore is not, nor is the use of polylysine for the binding substance.

On the other hand, Locher teaches a modified FhuA channel which can be made to allow large DNAs to pass (p. 771), and Cotton teaches that polylysine can bind to DNA (p. 12.3.1).

Moreover, it is inherent in the separations that the substance (DNA) to be isolated from the medium must necessarily be contacted with the vesicle.

Further, Official Notice is given that it is well known to add salt to separate charge-bound molecules, including polylysine. Also, Official Notice is provided that shear stress is known for destroying vesicles.

Hence, it would be further obvious to modify the method to utilize the FhuA of Locher, and the polylysine of Cotton. The Artisan would do so to separate DNA from the medium and bind it within the vesicle. Moreover, the Artisan would have a reasonable expectation of success, as each of the parts are utilized for art-recognized purposes.

Use of Liposome

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., and Danelon, et al. (2003) Journal

of Biological Chemistry, 278(37): 35542-51, as applied to claims 1-5 and 8 above, and further in view of U.S. Patent No. 6,958,160 to Keller, et al. and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87.

As shown above, the base claims are obviated, but the use of an enantioselective channel is not.

As shown above, the various references obviate the claims, but fail to teach the use of liposomes for use in the method as the vesicle.

On the other hand, liposomes are known in the Art, and utilized for containing and studying membrane-bound proteins, and for containing molecules for delivery. For Example, Keller teaches lipsomes for drug delivery, including nucleic acids (e.g., Claim 5) and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87 teaches the use of liposomes to study transmembrane protein behavior of hydrophobic peptides.

From this, given the similar structure and known ability to incorporate proteins into the membranes of liposomes, it would be further obvious to utilize a liposome to perform the purifications/isolations. The Artisan would do so given their similar structure and ability to separate the substances. Moreover, the Artisan would expect success, as the components are utilized for art-recognized purposes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., Locher, et al. (1998) Cell, 95: 771-78 and Cotton, et al. (2001) Current Protocols in Human Genetics, Chapter 12, Unit 12.3, Supplement 11, Wiley Online Library, 12.3.1-12.3.33, John Wiley & Sons, Inc., as applied to claims 1-4 and 6-11, above, and further in view of U.S. Patent No. 6,958,160 to Keller, et al. and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87.

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From this, given the similar structure and known ability to incorporate proteins into the membranes of liposomes, it would be further obvious to utilize a liposome to perform the purifications/isolations. The Artisan would do so given their similar structure and ability to separate the substances. Moreover, the Artisan would expect success, as the components are utilized for art-recognized purposes.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633